DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FEB 7 2007

Re: S8 Over-the-Wire System

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the following applications for patent term extension filed by Medtronic Vascular, under 35 U.S.C. § 156 et seq.

Product	Patent Number	Docket Number
S8 Over-the-Wire System	5,292,331	2004E-0304
S8 Over-the-Wire System	5,800,509	2004E-0300
S8 Over-the-Wire System	5,836,965	2004E-0306
S8 Over-the-Wire System	5,879,382	2004E-0303
S8 Over-the-Wire System	5,891,190	2004E-0301
S8 Over-the-Wire System	6,159,229	2006E-0206
S8 Over-the-Wire System	6,309,402	2004E-0302
S8 Over-the-Wire System	6,344,053	2004E-0426

We have reviewed the dates contained in the applications and have determined the regulatory review period for S8 Over-the-Wire System, the medical device claimed by the patents.

The total length of the regulatory review period for S8 Over-the-Wire System is 652 days. Of this time, 477 days occurred during the testing phase and 175 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act involving this device became effective: December 20, 2001.

   FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act for human tests to begin became effective on December 20, 2001.

2. The date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act: April 10, 2003.

The applicant claims April 9, 2003, as the date the premarket approval application (PMA) for the S8 Over-the-Wire System (PMA P030009) was initially submitted. However, FDA records indicate that PMA P030009 was submitted on April 10, 2003.

3. The date the application was approved: October 1, 2003.

FDA has verified the applicant's claim that PMA P030009 was approved on October 1, 2003.

This determination of the regulatory review period by FDA does not take into account the effective date of the patents, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Michael J. Jaro
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